2007

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21!

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 84-R-0051
CUSTOMER NUMBER: 1273

FORM APPROVED
OMB NO. 0579-0036

Genesis Laboratories, Inc.
10122 N.E. Frontage Road
Wellington, CO 80549

Telephone: (970) -568-7059

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY **(Attach additional sheets if necessary or use APHIS Form 7023A)**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Wild Norway Rats	40	29	0	26	55
Meadow Vole	0	0	0	25	25
WY Ground Squirrel	0	6	0	15	21

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

MAR 10

SI

(b)(6),(b)(7)(c)

(b)(6),(b)(7)(c)

DATE SIGNED 3/5/08

AP

obsolete.)

(AUG 91)

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

2007

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 1273 84 R0057

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*
Genesis Laboratories, Inc.

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations 12. &/OR 13. Other *(List by species)*	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).*	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
Black-tailed Prairie Dog	0	1	0	30	31
Nutria	0	0	5	50	55
N. Pocket Gopher	7	8	0	0	8

ASSURANCE STATEMENTS

1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2). Each principal investigator has considered alternatives to painful procedures.

3). This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4). The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
(b)(6),(b)(7)(c)	(b)(6),(b)(7)(c)	3/5/08

(AUG 91)

PART 1 - HEADQUARTERS

ANNUAL REPORT OF ANIMALS USED BY GENESIS LABORATORIES, INC.
DURING THE 12 MONTH PERIOD OCTOBER 1, 2006 TO SEPTEMBER 30, 2007

HEADQUARTERS OF RESEARCH FACILITY	FACILITY LOCATIONS
GENESIS LABORATORIES, INC. 10122 N. E. FRONTAGE ROAD WELLINGTON, COLORADO 80549 Registration # 84-R-051	(b)(2)High, (b)(7)(F) Registration #: 84-R-051

ANIMALS REPORTED IN COLUMN E

Wild Norway Rat (*Rattus norvegicus*)

Twenty-six (26) rats used are being reported in column E of the Annual Report. Two animals used died from stress due to capture and transport into individual cages. The other 24 animals used were used in studies testing rodenticides. These animals were used for testing a rodenticide via feed trials and death of the rodent is the end point.

FIFRA mandates that efficacy data be generated to support label claims for rodent control. No anesthetics, analgesics, or tranquilizing drugs were used to relieve the pain. Animals displaying toxicosis were not euthanized. The USEPA policy on rodenticide testing (Attachment 1) forbids the use of pain-relieving drugs and premature euthanasia. Use of such drugs or procedures would negate the study. There are no alternatives available to this painful procedure. The only alternative to administration of a toxic product (which is intended to kill animals, and cause unavoidable pain in that process) is not to administer the toxic product. Poisonous substances cause tissue damage, which results in pain perception. One potential alternative is to develop products which create unconsciousness or analgesia prior to death. However, information is not yet available to design such products, which would be effective for rodent control.

USEPA, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Pesticide Assessment Guideline Subdivision G, Section 96-10, Commensal Rodents, was followed during these procedures.

Meadow Vole (*Microus pennsylvanicus*)

Twenty-five (25) rats used are being reported in column E of the Annual Report. All animals used were used in studies testing rodenticides. These animals were used for testing a rodenticide via feed trials and death of the rodent is the end point.

FIFRA mandates that efficacy data be generated to support label claims for rodent control. No anesthetics, analgesics, or tranquilizing drugs were used to relieve the pain. Animals displaying toxicosis were not euthanized. The USEPA policy on rodenticide testing (Attachment 1) forbids the

use of pain-relieving drugs and premature euthanasia. Use of such drugs or procedures would negate the study. There are no alternatives available to this painful procedure. The only alternative to administration of a toxic product (which is intended to kill animals, and cause unavoidable pain in that process) is not to administer the toxic product. Poisonous substances cause tissue damage, which results in pain perception. One potential alternative is to develop products which create unconsciousness or analgesia prior to death. However, information is not yet available to design such products, which would be effective for rodent control.

USEPA, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Pesticide Assessment Guideline Subdivision G, Section 96-12, Rodenticides on Farm and Rangelands, was followed during these procedures.

Testing Rational and Background for the use of Wyoming Ground Squirrels and Black-tailed Prairie Dogs

Genesis Laboratories, Inc. under the funding of a Small Buiseness Innovative Research Grant from the Centers for Disease Control were funded for the development of an innovative rodent and flea control bait. With traditional rodenticides fleas are not controlled. When a rodent harboring fleas dies the fleas are left with looking for a new host for a blood meal. This new product incorporates an insecticide along with a rodenticide that kills fleas obtaining a blood meal from the rodent prior to killing the rodent. When laboratory studies were performed on laboratory rats was found that the inclusion of the rodenticide along with the insecticide confounded the results. This was due to the rodenticides increased efficacy, due to handling the rodents. Through many discussions with USEPA it was decided that to evaluate the insecticide, testing should be done without a rodenticide in the bait. Their view was to evaluate the insecticides potential at controlling/killing a pest (fleas) the same as is required to control a rodent with a rodenticide. The techniques to evaluate flea efficacy were designed to minimize stress to the mammal. The use of gavaging was incorporated to deliver a know amount of insecticide to the mammal, to evaluate flea efficacy at a specific dose. After a mammal was dosed, flea-feeding chambers were attached to them for approximately 3 hours. After that period the chambers were removed and flea efficacy was measured. It was discussed (verbally) with the EPA to not use any anesthetic/analgesic during this process due to the potential that it would effect the insecticide in the same manner that they effect a rodenticide. The studies have succeeded in a USEPA Sect. 3 Registration of a bait. This bait has the benefit of reducing flea populations along with the reduction or the rodents. The importance to this product is in the reduction of plague and plague outbreaks associated with the rodents.

Wyoming Ground Squirrels (*Spermophilus elegans)*

Fifteen (15) Wyoming ground squirrels used are being reported in column E of the Annual Report. All animals used were used in studies testing an insecticide. The unrelieved stress and/or pain associated with the ground squirrels were from manual restraint, gavaging, and a 3 hour period when flea feeding chambers were attached to the squirrels. The total duration of unrelieved pain and/or distress was approximately 4 hours. All animals were euthanized prior to blood collection. Animals did not display signs of toxicosis prior euthanized.

FIFRA mandates that efficacy data be generated to support label claims for pest control. No anesthetics, analgesics, or tranquilizing drugs were used to relieve the distress or pain in the ground squirrels during testing. The USEPA policy on rodenticide testing (Attachment 1) forbids the use of pain-relieving drugs and premature euthanasia. This does not directly state insecticides, but their view was the same with an insecticide killing an insect. Use of such drugs or procedures would negate the study. There are no alternatives available to this stressful and/or painful procedure. The only alternative to administration of a product (which is intended to kill parasitizing ectoparasites of animals) is not to evaluate the toxic product. The evaluation of substances causes unrelieved stress and/or pain under laboratory settings. One potential alternative is to evaluate such products under field conditions only, which would not cause stress and/or pain to the animals. However, information is not yet available to design such studies, which would provide the information being required by the US EPA.

USEPA, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Pesticide Assessment Guideline Subdivision G, Section 95-9, Treatments to Control Pests of Humans and Pets, and OPP 1.213 guideline, were followed during these procedures.

Black-tailed Prairie Dogs *(Cynomysludovicianus)*

Thirty (30) black-tailed prairie dogs used are being reported in column E of the Annual Report. All animals used were used in studies testing an insecticide. The unrelieved stress and/or pain associated with the prairie dogs were from manual restraint, gavaging, and a 3 hour period when flea feeding chambers were attached to the prairie dogs. The total duration of unrelieved pain and/or distress was approximately 4 hours. All animals were euthanized prior to blood collection. Animals did not display signs of toxicosis prior euthanized.

FIFRA mandates that efficacy data be generated to support label claims for pest control. No anesthetics, analgesics, or tranquilizing drugs were used to relieve the distress or pain in the prairie dogs during testing. The USEPA policy on rodenticide testing (Attachment 1) forbids the use of pain-relieving drugs and premature euthanasia. This does not directly state insecticides, but their view was the same with an insecticide killing an insect. Use of such drugs or procedures would negate the study. There are no alternatives available to this stressful and/or painful procedure. The only alternative to administration of a product (which is intended to kill parasitizing ectoparasites of animals) is not to evaluate the toxic product. The evaluation of substances causes unrelieved stress and/or pain under laboratory settings. One potential alternative is to evaluate such products under field conditions only, which would not cause stress and/or pain to the animals. However, information is not yet available to design such studies, which would provide the information being required by the US EPA.

USEPA, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Pesticide Assessment Guideline Subdivision G, Section 95-9, Treatments to Control Pests of Humans and Pets, and OPP 1.213 guideline, were followed during these procedures.

Nutria *(Myocastor coypus)*

Fifty (50) nutria used are being reported in column E of the Annual Report. All animals used were

used in studies testing rodenticides. These animals were used for testing a rodenticide via feed trials and death of the rodent is the end point.

FIFRA mandates that efficacy data be generated to support label claims for rodent control. No anesthetics, analgesics, or tranquilizing drugs were used to relieve the pain. Animals displaying toxicosis were not euthanized. The USEPA policy on rodenticide testing (Attachment 1) forbids the use of pain-relieving drugs and premature euthanasia. Use of such drugs or procedures would negate the study. There are no alternatives available to this painful procedure. The only alternative to administration of a toxic product (which is intended to kill animals, and cause unavoidable pain in that process) is not to administer the toxic product. Poisonous substances cause tissue damage, which results in pain perception. One potential alternative is to develop products which create unconsciousness or analgesia prior to death. However, information is not yet available to design such products, which would be effective for rodent control

USEPA, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Pesticide Assessment Guideline Subdivision G, Section 96-10, Commensal Rodents, was followed during these procedures.

ATTACHMENT 1

The following is an e-mail response from (b)(6),(b)(7)(c) of the USEPA, explaining his agencies position on the use of pain-relieving drugs or premature euthanasia in pesticide efficacy studies involving rodents. The e-mail was in response to a request by (b)(6),(b)(7)(c) at Genesis Laboratories, to state in writing and clarify the agency policy. Genesis Laboratories had been asked by APHIS, in 2004, to provide more detailed information on why pain relievers were withheld and why death was used as an endpoint in pesticide efficacy studies.

July 6, 2004:

"The issue of euthanasia was not mentioned in the "current" version of the [Pesticide Assessment] *Guidelines because it had not come into play with respect to efficacy testing protocols at that time. The Animal Welfare Act had been passed in the early 1970's, but there was common understanding that it was not to intrude upon the integrity of research. In efficacy studies involving toxicants, there must be a yes-or-no answer as to whether the poison killed the animal.*

The first instance that I remember encountering an efficacy protocol in which euthanasia was proposed happened in 1988. In that particular case, it appeared that the researchers were so intent on addressing euthanasia that they completely forgot what the research was about. In the course of reviewing that protocol, I drafted a response the gist of which was that the nature of the research was such that it was absolutely necessary to determine whether the poison killed the animal, that animals that recovered from having been poisoned with the rodenticide in question were not only likely to be the founders of the rebounding population but also would be behaviorally resistant (i.e., bait shy) to any bait containing the compound used in the initial trial. (The compound in question was an acute rodenticide.) Those are extremely important things to know about a rodenticide. I may have added that evidence indicating that a rodenticide routinely causes suffering should be considered in determining its suitability for future research and use

I currently am revising the Guidelines and plan to address the issue of euthanasia much as I did in 1988, adding only that it would be permissible to euthanize seemingly moribund animals if not only the event of poison-caused death but also the time to death could be predicted with virtual certainty. This is a very tricky area, however. If we were to register a rodenticide based upon the results of laboratory and field trials in which eager-to-please personnel collected and dispatched every target rodent that they could get their hands on as

soon as the animals appeared to be affected to any degree, we might wind up with a real turkey of a rodenticide on the market. A circumstance not quite so extreme but certainly affecting some of the results that were reported occurred a while back and was only discovered when one researcher decided to collect symptomatic animals and cage them to see whether they would recover or die. Many of them recovered. Ultimately, it was determined that the active ingredient concentration needed in baits was double that which was used in the original field testing.

If I received a report of a laboratory efficacy trial in which it were stated that animals were "humanely dispatched", I would reject the study flat out. Percent mortality is the dependent variable in those trials. Adding additional causes of mortality would render the study useless as efficacy research.

In the case of the Genesis ground squirrel field trials to which you alluded, it seemed to me that field personnel may have been too eager to euthanatize animals. I recall a line in the report that said, in effect, that personnel dispatched every squirrel that they could catch but some "were able to slip down their burrows" (approximate quote) before they could be caught. Animals capable of slipping "down their burrows" would not seem to be moribund by anyone's definition, and I recall having responded to that.

If it is decided that a candidate rodenticide causes so much pain that it should not be considered for further use, then animals on test should be euthanatized and the results should be written up, not so much as an efficacy study, but as research aborted for humane reasons. Apart from that, I see no proper role for analgesics in rodenticide research. Rodenticide efficacy trials basically are behavioral studies. The effects of the candidate compound must be assessed isolated from other factors which might distort the observations and, of course, the animal's viability and ability to make adaptive responses -- such as slipping down a burrow. There is no way to sensibly use analgesics in field trials of rodenticide baits that would not be likely to interfere with behavior and viability. Even if the animals die after they "slip down their burrows", it is important that they are able to as where they die affects the determination of percent surface kill and the degree to which carcasses are available to nonfossorial scavengers and predators (such as avian raptors).

When we attempt to impose human values on animals' circumstances, we risk deluding ourselves. In general, wild animals are all about survival and will do whatever it takes (even chewing off their own feet) to last as long as they can. (Tranquilizer tabs associated with leg-hold traps turned out to be a good idea because some animals were

spared further, self-inflicted, injuries on top of what the traps did to them. That, however, is a really exceptional case; and one which does not involve a vertebrate pesticide.) There also has been some discussion of whether what appears to be distress is consciously perceived by the animal. Some of the older rodenticides produce symptoms which clearly look like distress, although humans exposed to the same compounds sometimes had little recollection of the experience. Some have suggested that anticoagulants, with their protracted times to death, "must" be inhumane. However, some humans who have bled severely internally (for one reason or another) have reported little or no discomfort and sought help only because of other symptoms (e.g., lethargy, evidence of occult blood, loss of function, etc.)."

(b)(6),(b)(7)(c)